DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 20, 2017

JiangXi HongDa Medical Equipment Group Ltd.
c/o Ms. Diana Hong
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
CHINA

Re: K163162
Trade/Device Name: Sterile Hypodermic Safety Syringes for Single Use
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG, FMI
Dated: February 14, 2017
Received: February 15, 2017

Dear Ms. Diana Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163162

Device Name
Sterile Hypodermic Safety Syringes for Single Use

Indications for Use *(Describe)*
The Sterile Hypodermic Safety Syringes for Single Use is intended to be used for medical purpose to inject fluids into or withdraw fluids from the body. After injection, the anti-needlestick feature is manually activated to aid in the prevention of accidental needle stick injuries.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K163162

1. Date of Preparation: 03/15/2017

2. Sponsor Identification

JiangXi HongDa Medical Equipment Group Ltd.
No. 39 South Shengli Road, Jinxian County, Nanchang City,
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
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Fax: 240-238-7587
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Sterile Hypodermic Safety Syringes for Single Use
Common Name: Piston Syringe with Needle

Regulatory Information
Classification Name: Syringe Antistick
Classification: II
Product Code: MEG
Subsequent Product Code: FMI
Regulation Number: 21 CFR 880.5860
Review Panel: General Hospital

Indication for Use:
The Sterile Hypodermic Safety Syringes for Single Use is intended to be used for medical purpose to inject fluids into or withdraw fluids from the body. After injection, the anti-needlestick feature is manually activated to aid in the prevention of accidental needle stick injuries.

Device Description

The proposed devices are for single use only, which are comprised of syringes and needles with various specifications. The proposed devices are available in a variety combination of needle sizes and syringe volumes. All specifications of proposed devices subject to the same design. The proposed devices are intended for manual use only.

5. Identification of Predicate Device

510(k) Number: K072739
Product Name: Retractable Auto-Disable Syringe for single use, with/without needle

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test provided in this submission include:

Physical, Mechanical and Chemical Tests performed on the proposed device

Materials	Clause 3 of ISO 9626:1991/AMD-1:2001
Surface finish	Clause 4 of ISO 9626:1991/AMD-1:2001
Cleanliness	Clause 5 of ISO 9626:1991/AMD-1:2001

Limits for acidity and alkalinity	Clause 6 of ISO 9626:1991/AMD-1:2001
Size designation	Clause 7 of ISO 9626:1991/AMD-1:2001
Dimensions	Clause 8 of ISO 9626:1991/AMD-1:2001
Stiffness	Clause 9 of ISO 9626:1991/AMD-1:2001
Resistance to breakage	Clause 10 of ISO 9626:1991/AMD-1:2001
Resistance to corrosion	Clause 11 of ISO 9626:1991/AMD-1:2001
Cleanliness	Clause 4 of ISO 7864:1993
Limits for acidity or alkalinity	Clause 5 of ISO 7864:1993
Limits for extractable metals	Clause 6 of ISO 7864:1993
Size designation	Clause 7 of ISO 7864:1993
Colour coding	Clause 8 of ISO 7864:1993
Needle hub	Clause 9 of ISO 7864:1993
Sheath	Clause 10 of ISO 7864:1993
Needle tube	Clause 11 of ISO 7864:1993
Needle point	Clause 12 of ISO 7864:1993
Performance	Clause 13 of ISO 7864:1993
Cleanliness	Clause 5 of ISO 7886:1993
Limits for acidity or alkalinity	Clause 6 of ISO 7886:1993
Limits for extractable metals	Clause 7 of ISO 7886:1993
Lubricant	Clause 8 of ISO 7886:1993
Tolerance on graduated capacity	Clause 9 of ISO 7886:1993
Graduated scale	Clause 10 of ISO 7886:1993
Barrel	Clause 11 of ISO 7886:1993
Piston/plunger assembly	Clause 12 of ISO 7886:1993
Nozzle	Clause 13 of ISO 7886:1993
Performance	Clause 14 of ISO 7886:1993
Dimension	Clause 3 of ISO 594-1:1986
Gauging	Clause 4.1 of ISO 594-1:1986
Liquid leakage	Clause 4.2 of ISO 594-1:1986
Air leakage	Clause 4.3 of ISO 594-1:1986
Separation force	Clause 4.4 of ISO 594-1:1986
Stress cracking	Clause 4.5 of ISO 594-1:1986
Gauging	Clause 4.1 of ISO 594-2:1998
Leakage	Clause 4.2 of ISO 594-2:1998
Separation force	Clause 4.3 of ISO 594-2:1998
Unscrewing torque	Clause 4.4 of ISO 594-2:1998

Ease of assembly	Clause 4.5 of ISO 594-2:1998
Resistance to overriding	Clause 4.6 of ISO 594-2:1998
Stress cracking	Clause 4.7 of ISO 594-2:1998

Sterile Barrier Packaging Testing performed on the proposed device:

Seal strength	ASTM F88/F88-09
Internal pressure	ASTM F1140/F1140M-13

Sterilization and Shelf Life Testing performed on the proposed device:

EO residue	ISO 10993-7:2008
ECH residue	ISO 10993-7:2008
Sterility test	ISO 11737-2: 2009
Bacteria Endotoxin Limit	USP 36-NF 31<85>
Shelf Life Evaluation	Physical, Mechanical, Chemical, Package and Sterility Tests were performed on real time aging samples to verify the claimed shelf life of the device

Biocompatibility Testing

The patient-contact materials of Sterile Hypodermic Safety Syringes for Single Use are identified and biocompatibility testing is performed according to ISO 10993 standards

Simulated Clinical Study

A simulated clinical study was performed on proposed device according to FDA Guidance, Guidance for Industry and FDA Staff: Medical Device with Sharps Injury Prevention Feature, issued on August 9, 2005 to evaluate the safety mechanism of the proposed device. The results demonstrated that the proposed device met the pre-established criteria.

Safety Feature Test

The safety feature test was performed on both proposed device and predicate device to determine its safety feature. The results demonstrated that the proposed device did not show a significant difference from predicate device.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device		Predicate Device K072739
Product Code	MEG		Same
Regulation Number	21 CFR 880.5860		Same
Class	II		Same
Indication for Use	The Sterile Hypodermic Safety Syringes for Single Use is intended to be used for medical purpose to inject fluids into or withdraw fluids from the body. After injection, the anti-needlestick feature is manually activated to aid in the prevention of accidental needle stick injuries.		Similar
Configuration and material	Barrel	Polypropylene (PP)	Same
	Plunger	Polypropylene (PP)	
	Piston	Polyisoprene	
	Needle hub	Polypropylene (PP)	
	Needle cap	Polypropylene (PP)	
	Needle tube	Stainless Steel, SUS304	
Operation Mode	For manual use only		Same
Syringe Volume	5ml		3ml, 5ml, 10ml
Connector Type	Luer Lock		Same
Needle Gauge and Length	Gauge:21G, 22G, 23G Length: 1", 1 1/4", 1 1/2"		Similar
Biocompatibility	Cytotoxicity	No cytotoxicity	Same
	Irritation	No intracutaneous reactivity	
	Sensitization	No skin sensitization	
	Systemic Toxicity	No systemic toxicity	
	Hemolysis	No Hemolysis	
	Pyrogen	No Pyrogen	
Sterilization	EO Sterilization		Same
SAL	10^{-6}		Same

Single Use	Yes	Same
Label/Labeling	Complied with 21 CFR part 801	Same

The Sterile Hypodermic Safety Syringe for Single Use is similar to the predicate device in device design, Indications for use, materials, sterilization, method of operation and technological characteristics. The differences are in needle lengths/gauges and barrel sizes. The predicate device submission K072739 also includes insulin syringes and non-safety syringes but the subject device is claiming substantial equivalence to the predicates safety syringe. Through performance testing comparison the subject device and predicate device have demonstrated substantial equivalence.

9. Substantially Equivalent (SE) Conclusion

Based on the bench performance testing, comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.